IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

5. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") is a corporation organized and existing under the laws of India, with a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, Telenangana 50034, India.

6. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") is a corporation organized under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

7. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

8. On information and belief, Dr. Reddy's Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug

products. As a part of this business, upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. act in concert to file ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Dr. Reddy's Inc., acting on behalf of Dr. Reddy's Ltd., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to prepare and submit ANDA No. 208534 for Dr. Reddy's 2.5 mg rivaroxaban tablets ("Dr. Reddy's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Dr. Reddy's Ltd.

10. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Dr. Reddy's ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 208534, Dr. Reddy's Ltd. and Dr. Reddy's Inc. will act in concert to market, distribute, offer for sale, and sell Dr. Reddy's ANDA Product throughout the United States and within Delaware.

These entities—Dr. Reddy's Ltd. and Dr. Reddy's Inc.—are hereafter collectively referred to as "Dr. Reddy's."

12. On information and belief, following any FDA approval of ANDA No. 208534, Dr. Reddy's knows and intends that Dr. Reddy's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Dr. Reddy's Ltd. and Dr. Reddy's Inc. because, among other things, on information and belief: (1) Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to file an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's ANDA Product in the United States, including in Delaware; and (2) Dr. Reddy's Ltd. and Dr. Reddy's Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Dr. Reddy's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208534, and will derive substantial revenue from the use or consumption of Dr. Reddy's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 208534 is approved, the generic Dr. Reddy's product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within

Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

16. Alternatively, if Dr. Reddy's Ltd.'s connections with Delaware, including its connections with Dr. Reddy's Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Dr. Reddy's Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Dr. Reddy's Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

17. Dr. Reddy's Ltd. and Dr. Reddy's Inc. have consented to jurisdiction in Delaware in multiple prior cases arising out of the filings of their ANDAs, and have filed counterclaims in some such cases. *See, e.g.*, *Intercept Pharmaceuticals, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 21-35 (D.I. 10); *Astellas US LLC et al. v. Apotex Inc., et al.*, C.A. No. 18-1675 (consolidated) (D.I. 129); *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 16-1011 (D.I. 11); *Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-1283 (D.I. 9); *Pfizer, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 09-943 (D.I. 9).

VENUE

18. Venue is proper in this district for Dr. Reddy's Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Dr. Reddy's Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district and/or will consent to venue for the purpose of this case. *See, e.g.*, *Intercept Pharmaceuticals, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 21-35 (D.I. 10); *Astellas US LLC et al. v. Apotex Inc., et al.*, C.A. No. 18-1675 (consolidated) (D.I. 129); *Onyx Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc. et al.*,

C.A. No. 16-1011 (D.I. 11); *Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-1283 (D.I. 9); *Pfizer, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 09-943 (D.I. 9).

19. Venue is proper in this district for Dr. Reddy's Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Dr. Reddy's Ltd. is a private limited company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

20. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

21. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

22. The '310 patent, entitled "Reducing the Risk of Cardiovascular Events," was duly and legally issued on November 10, 2020. The '310 patent is attached as Exhibit A.

23. As set forth in greater detail in the '310 patent, the claims of the '310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, "A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial

disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

24. Bayer Pharma AG is the assignee of the '310 patent.

25. Bayer AG is an exclusive licensee under the '310 patent.

26. Janssen is an exclusive sublicensee under the '310 patent.

27. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

COUNT I: INFRINGEMENT OF THE '310 PATENT

28. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

29. By letter dated April 14, 2021 ("Dr.Reddy's Notice Letter"), Dr. Reddy's notified, *inter alia*, Plaintiffs that Dr. Reddy's Inc., on behalf of Dr. Reddy's Ltd., had submitted to the FDA ANDA No. 208534 for Dr. Reddy's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

30. In Dr. Reddy's Notice Letter, Dr. Reddy's indicated that, in connection with its ANDA No. 208534, Dr. Reddy's had filed, *inter alia*, a Paragraph IV Certification with respect to the '310 patent.

31. In Dr. Reddy's Notice Letter, Dr. Reddy's stated that Dr. Reddy's ANDA Product contains rivaroxaban.

32. On information and belief, the proposed labeling for Dr. Reddy's ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for

Dr. Reddy's ANDA Product further directs the administration of Dr. Reddy's ANDA Product and aspirin in amounts that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Dr. Reddy's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

33. The purpose of ANDA No. 208534 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Dr. Reddy's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

34. Dr. Reddy's intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208534, *i.e.*, prior to the expiration of the '310 patent.

35. On information and belief, the manufacture, use (including in accordance with and as directed by Dr. Reddy's proposed labeling for Dr. Reddy's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product will infringe at least claim 1 of the '310 patent.

36. In Dr. Reddy's Notice Letter, Dr. Reddy's did not contest that the use of Dr. Reddy's ANDA Product in accordance with its proposed labeling would infringe the '310 patent.

37. Dr. Reddy's has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Dr. Reddy's has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA

No. 208534. On information and belief, by such activities, Dr. Reddy's specifically intends to infringe the '310 patent.

38. On information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. On information and belief, Dr. Reddy's knows that Dr. Reddy's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Dr. Reddy's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. On information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 208534.

40. Dr. Reddy's submission of ANDA No. 208534 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Dr. Reddy's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

41. On information and belief, Dr. Reddy's has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Dr. Reddy's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

42. Dr. Reddy's intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

43. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

44. Unless Dr. Reddy's is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

45. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received Dr. Reddy's Notice Letter.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

46. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

47. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Dr. Reddy's on the other regarding Dr. Reddy's liability for infringement and active inducement of infringement of the '310 patent.

48. An actual case or controversy exists between Plaintiffs and Dr. Reddy's with respect to Dr. Reddy's liability for infringement of the '310 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Dr. Reddy's ANDA Product will infringe and induce the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Dr. Reddy's has infringed the '310 patent;

(b) A judgment ordering that the effective date of any FDA approval for Dr. Reddy's to make, use, offer for sale, sell, market, distribute, or import Dr. Reddy's ANDA Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Dr. Reddy's, and all persons acting in concert with Dr. Reddy's, from making, using, selling, offering for sale, marketing, distributing, or importing Dr. Reddy's ANDA Product, or any product or compound the use of which infringes the '310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Dr. Reddy's ANDA Product prior to the expiration of the '310 patent will infringe and induce the infringement of the '310 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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